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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,458	08/01/2003	Sophie Chen	CSO-0001-P	2036

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EXAMINER	
SIMMONS, CHRIS E	
ART UNIT	**PAPER NUMBER**
1612	

NOTIFICATION DATE	DELIVERY MODE
10/14/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/647,458	CHEN, SOPHIE	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-7,19-23,26-29,32-36,38,39 and 44-51* is/are pending in the application.

4a) Of the above claim(s) *4,8-17,25,31,37 and 40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,19-23,26-29,32-36,38,39 and 44-51* is/are rejected.

7)☒ Claim(s) *5-7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

After reconsideration of applicant's election of Group I in the reply filed on 01/17/2006, the examiner agrees with applicant's most recent remarks in the amendment filed on 05/16/2008 that claims 7, 38 and 39 should not be withdrawn. Claims 7, 38 and 39 are no longer considered withdrawn.

Claim Rejections - 35 USC § 112

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are incomplete (and thus indefinite) since depend (directly or ultimately) from a deleted claim. Accordingly, they will be interpreted, for examination purposes, as if they depend from independent claim 1.

Maintained Obviousness Rejections

Claims 1-2, 5-7, 19, 20-23, 26-29, 32, 34-36, 38 and 39 were rejected under 35 USC 103(a) as being unpatentable over JP-09-176011 in view of USP 6,498,188.

This rejection is maintained.

Applicant argues that the JP reference does not show treatment in humans and therefore, does not suggest treatment in humans. This is not persuasive because the JP reference discloses positive results showing anticancer effectiveness of human cancer cells. It would, therefore, be obvious to eventually upgrade the study/treatment into animals, including humans.

Applicant further argues that wogonin is not used to treat cancer per se but is used to control HSP 27 expression. This is not persuasive because the reference clearly suggests that such control of HSP 27 results in effectiveness cancer treatment. Applicant admits that the reference wogonin is disclosed to "reinforce the effectiveness of chemotherapy". The examiner believes this corroborates the examiner's belief that the reference, indeed, suggest treatment of cancer using wogonin to at *least* "reinforce" chemotherapy. The examiner further believes that to "reinforce the effectiveness of chemotherapy" comprises treatment of cancer.

Applicant further criticizes the secondary reference alleging that it does not disclose combination therapy and further alleges the reference only discloses that carbamates and thiocarbamates kill cells.

As for the unexpected results, alleged by applicant, the examiner notes that there is no proper showing of unexpected results. There is no side-by-side comparison of unexpected data. In the case that applicant did show unexpected results, purely in arguendo, the results demonstrated in TABLE 3 only shows effects on PSA - which is not commensurate in scope with the pending claims.

New Obviousness Rejections

Claims 1-2, 5-6, 19, 20, 22, 23, 26, 29, 32, 34, 36 and 38 are rejected under 35 USC 103(a) as being unpatentable over JP-09-176011 in view of USP 6,413,535.

The disclosure of the primary reference is outlined in the previous office action submitted on 11/16/2007. It does not explicitly teach specific dosages for wogonin in combination with an immunomodulator or a second anticancer compound that is not a phytoestrogen.

The secondary reference discloses a method for chemoprevention of prostate cancer using compositions comprising therapeutically effective amounts of prostate chemotherapeutic agents (e.g., coumestrol; col. 5, ll. 11-14 and 21) in combination therapy with therapeutically effective amounts of DNA damaging agents, such as cisplatin, using protocols and methods which are well known in the art. DNA damaging agents and factors are known to those skilled in the art and encompass any chemical or treatment method known that induces DNA damage when applied to a cell (col. 10, ll. 44-50, 59 and 60). The composition contains therapeutically effective amounts of the

agent together with suitable adjuvant, diluents, preservatives, solubilizers, etc. The term "adjuvant" refers to a compound or mixture that enhances the immune response to an antigen (col. 7, ll. 1-4, 63 and 64). The reference does not explicitly teach wogonin. “Therapeutic effective amount” refers to that amount which provides a therapeutic effect for a given condition and administration regimen (col. 7, ll. 4-7). The dosage may be in the range of 20-80 mg/day (col. 7, ll. 38-39).

It would have been obvious to one of ordinary skill in the art to combine the ingredients (i.e., the prostate chemotherapeutic agent, DNA damaging agent, and adjuvant) of the secondary reference to the composition of the primary reference since motivation would stem from the reasonable expectation of treating cancer with a combination of drugs already known to be useful for the treatment of cancer. Generally, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. Conversely, there is no evidence in the record establishing the Applicant's combination of agents is any more effective or in any way different than any single member of that combination. MPEP 2144.06. In this case, each ingredient is disclosed as being useful for treating cancer and, thus, combining them would flow logically from their individual disclosures.

Generally, it is not patentable to optimize the concentration of ingredients in a composition through routine experimentation. Differences in concentration from what is disclosed in the reference, will not support the patentability of subject matter

encompassed by the prior art unless there is evidence indicating such concentration is critical. It is not inventive to discover the optimum or workable ranges by routine experimentation. *See MPEP 2144.05 [R-5] II A*. In this case, the amount would be varied depending on the desired protocols and methods which are well known in the art.

Claims 21, 27, 35, 39, 50 and 51 are rejected under 35 USC 103(a) as being unpatentable over JP 09-176011 and USP 6,413,535 in view of JP 11-244597.

The disclosures of the primary and secondary references are outlined above. The combination does not expressly teach an extract of Ganoderma lucidum.

The tertiary reference discloses anticancer medicine comprising extract of Ganoderma lucidum (i.e., the immune stimulating agent) as the active agent (abstract). The reference does not expressly teach wogonin in combination with a second anticancer agent.

Again, it would have been obvious to one of ordinary skill in the art to combine the extract of Ganoderma lucidum from the secondary reference with the composition suggested by the combination of the primary and secondary references since motivation would stem from the reasonable expectation of treating cancer with a combination of drugs already known to be useful for the treatment cancer.

Claims 1-2, 5-7, 19, 20-23, 26, 27-29, 32-36, 38, 39, and 46-51 are rejected under 35 USC 103(a) as being unpatentable over USP 5,665,393.

Claims 1-2, 5-7, 19, 20-23, 26, 27-29, 32-36, 38, 39, and 46-51 are rejected under 35 USC 103(a) as being unpatentable over WO 98/09615.

Both references (USP 5,665,393 and WO 98/09615) disclose herbal compositions for treating prostate cancer (title). The treatment uses compositions comprising extracts from the following herbs: Panax pseudo-Ginseng (known source for ginsenosides), Ganoderma lucidum Karst, Glycyrrhiza glabra (known source for isoliquiritigenin), Scutelleria baicalensis Georgi (known source for wogonin), Rhabdosia rubenscens (known source for oridonin), and Sereno repens (abstract).

The reference does not expressly teach wogonin in the specifically claimed amounts. Generally, it is not patentable to optimize the concentration of ingredients in a composition through routine experimentation. Differences in concentration from what is disclosed in the reference, will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. It is not inventive to discover the optimum or workable ranges by routine experimentation. *See MPEP 2144.05 [R-5] II A.*

Claims 44 and 45 are rejected under 35 USC 103(a) as being unpatentable over US 2002/0182274.

The reference discloses methods of inhibiting cancer growth (e.g., ovarian cancer) using soy extract (abstract). Soy extract is known to promote immune function

[0036]. Within the scope of the present invention is an extract of a Chinese herb such as Scutellaria baicalensis Georgi (a known source for wogonin). Micronutrients are disclosed as having anticancer properties. The reference does not explicitly disclose instantly claimed amounts of wogonin or the immune stimulant and wogonin in combination with another non-phytoestrogen agent. However, it would have been obvious to one of ordinary skill in the art to combine the Scutellaria and soy extract with a micronutrient being motivated by the reasonable expectation that the resultant composition would have some effectiveness against cancer. As for the limitation, "**taxol-resistant** ovarian cancer", the resistance of the cancer to another known treatment provides motivation to try another known method disclosed in the prior art as potentially being effective in treating ovarian cancer. Accordingly, whether the ovarian cancer is taxol resistant or not, one of ordinary skill in the art would be motivated to use the method suggested in the reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 5-7, 19, 20-23, 26, 27-29, 32-36, 38, 39, and 46-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-9 of U.S. Patent No. 5,665,393. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented composition contains a source for wogonin (i.e., Scutellaria), immune stimulants (col. 1, ll. 41-48) and other non-phytoestrogen anticancer agents such as oridonin (i.e., Rabdosia). Therefore, it would have been obvious to use known extracts of the herbs used in the patent motivated by the reasonable expectation of successfully making a composition for use against prostate cancer.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612